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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,166	12/08/2000	Richard W. Compans	96-99	2363

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EXAMINER	
LI, BAO Q	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/733,166	COMPANS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26, 29, 34-38* is/are pending in the application.

4a) Of the above claim(s) *29 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26 and 34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 21-26, 29, 34-39 and 40 are pending.

Response to Amendment

This is response to the amendment B, paper No. 14, filed on April 09, 2002. Claims 1-20, 27-28, 30-33 and 41-61 are canceled. Claims 21, 23-24, 26, 34, 37 and 38 are amended.

This application contains claims 29 and 39 drawn to an invention non-elected group with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are reminded that the response filed on paper No. 14 has a typographical error for statement of call elation of claim 41-62 because the specification does not contain claim 62.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office action.

Claim Objections

The amendment filed 04/09/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material in claim 21, which is not supported by the original disclosure is as follows: an immunocomposition useful for providing **protection in a human or animal deficient in CD^{4+} T cells**.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 21-26, 34-38 and 40 are still rejected under 35 U.S.C. 112, second paragraph on the similar ground as stated in the previous office action.

Claim 21 is still vague and indefinite in that the metes and bonds of " a sialic acids binding component" are not defined. Applicants argue that the sailic acids binding component " is well known in the art, such as hemagglutinin (HN). This argument is respectfully considered. However, it is not found persuasive because this limitation cannot read into the claim and the

claim itself cannot define what the other sailic acid binding component is. The rejection is maintained.

Claims 21 and 38 are still rejected for the unclear recitation of " an inactivated or attenuated target cell or virus". Applicant asserted that specification has described the type of the treatment such as heat, formalin, beta-propiolacton treatment or series passage make the target cell or virus non-tumorigenic and replication defective, which is used within the art-recognized meaning. The rejection therefore, should be withdrawn.

Applicants' argument is fully considered. However, it is not found persuasive because some chemical treatment, such as formalin, will cause tumor cells or virus death rather than non-tumorigenic or attenuation. Series massage of virus may cause the tumor cell to be more tumorigenic or virus is more virulent. In addition, whether the cell being tumorigenic or non-tumorigenic is still active cell for its proliferation. Therefore, it is still unclear and confusing what the inactivated or attenuated target cell or virus is referred in the claims.

Moreover, the limitation as Applicants explained in the response cannot read into the claims and the claims cannot define themselves. Therefore, the rejection is maintained. This affects the dependent claims 22-26, 34-38 and 40.

Claims 24 and 38 are still unclear in that the metes and bonds of " a viral like particle" are not defined. Applicants assert that the viral like particle refers to a particle that resembles a given virus with respect to the size and structure but without the infectivity. This argument I respectfully considered, however, it is not found persuasive because the claim itself can not explain which viral like particle is intended since there are so many viral like particles in the art.

Claim 26 is still unclear although Applicants amend the claim to the virus preparation because the claim itself cannot define which antigen preparation of the said virus intended? Is whole HIV virus intended?

Claim 34 is still rejected for it's indefinite in that the metes and bonds of " a sialic acid binding component", " one antigen", a target cell" and "target virus" are all not defined. Although Applicants amend the claim, the claim itself still can not define what the metes and bonds of " a sialic acid binding component", " one antigen", a target cell" and "target virus". If Applicants wish to claim certain element of a virus, the claim should amend to reflecting the

precise component of certain virus and certain antigen of certain virus or tumor. The rejection is therefore, maintained.

Claim Rejections - 35 USC § 112

Claims 21-26, 34-38 and 40 are still rejected under 35 U.S.C. 112, first paragraph, on the similar ground as stated in the previous office action because the specification, while being enabling for using a formalin-inactivated influenza virus PR/8 for inducing the virus-specific IgM and IgG in the absence of $CD4^+$ T cell and completely protect the $CD4^+$-deficient mice from the lethal infection with live, pathogenic influenza virus, does not reasonably provide enablement for having an immunogenic composition comprising a sialic acid binding component and any or all inactivated or attenuated tumor cell or viruses or bacterial cells to produce a protective immunity in human and animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the present invention is a new discovery of vaccine compositions comprising sialic acid together with a sialic acid binding compositions as specifically exemplified by a formalin-inactivated influenza virus elicit protective immunity in CD4+ T cell independent manner. Applicants further asserted that specification provides evidence that injection of a formalin-inactivated influenza virus composition into a C57BL/6-$Cd4^{+tm/mak}$ induce anti-influenza virus antibody. Therefore, it is submitted that person of ordinary skill in the art is able to make the invention based on the disclosure of the present application.

Applicants' argument is respectfully considered; however, it is not found persuasive. First, the example taught in the specification can not approve that first the immune response induced by the claimed composition is exclusively due to the existence of the sialic acid component and sialic acid binding component in the composition because Applicants fails to show any evidence that the induced humoral immune response is due to a use of a composition consisting of silica acid and sialic acid binding component only. Because the composition used in the experiment contains lots of other components rather than sialic acid or sialic acid binding component. The conclusion that the induced serum immune response is due to the existence of the sialic acid and sialic acid binding component is just an assumption.

Furthermore, Applicants only show that a formalin inactivated influenza virus is able to induce an serum immune response in a CD4+ T cell knock-out mouse model, it do not teach a composition consisting of silica acid and sialic acid binding component can produce a protective immunity in animal or human.

In fact, the evidence provided by the previous office action strongly argues that the vaccine composition consisting essential of hemaggluttine, which consists essential of a sialic acid and sialic acid binding component, failed to induced any protective immunity in the CD4+ deficient AIDS patients. Although Applicants alleged that the composition used by Moitti et al. does not mention to contain the sialic acid and sialic acid binding component, the fact is that the composition used by Moitti et al is the same as the one used by Applicants in the specification. Therefore, it still suggests that the field is highly unpredictable.

Because Applicant failed to provide some evidenced to support the broadly claimed invention, the rejection still maintained.

Claim Rejections - 35 USC § 102

Claims 21-26, 34-38 and 40 are still rejected under 35 U.S.C. 102(b) as being anticipated by Compans (US Patent No. 4,790,987).

Applicants argue that the cited reference does not teach that the composition comprising sialic acid or sialic acid binding component. Applicants' argument is fully considered; however, it is not found persuasive because the fact is the composition disclosed in the specification is the same composition as taught by the prior art. Therefore, the rejection is maintained.

Claims 21-25, 34-38 and 40 are still rejected under 35 U.S.C. 102(b) as being anticipated by Pertmer et al. (J. Virol. 1996, Vol. 70, pp. 5119-6125).

Applicants argue that the composition disclosed by the cited reference only compared the result of DNA vaccine. Applicants' argument is fully considered; however, it is not found persuasive because Pertmer et al. teach to use a formalin-inactivated influenza virus comprising a hemagglutinin to immunize the mice to produce INF-γ, IL-4 and different classes of the IgG against Influenza neocleoprotein. The hemagglutinin is in the sialic acid binding component and the virus is the formalin-inactivated virus. Therefore, the rejection is maintained.

Claims 21-26, 34-38 and 40 are still rejected under 35 U.S.C. 102(b) as being anticipated by Muster et al. (J. Virol. 1994, Vol. 68, pp. 4031-4034).

Applicants argue that the cited reference does not teach that the composition comprising sialic acid or sialic acid binding component. Applicants' argument is fully considered; however, it is not found persuasive because the fact is the composition disclosed in the Muster et al' reference comprising a chimeric influenza virus, in which hemagglutinin of a influenza virus inserted with a HIV envelope protein gp41 sequence of ELDKWA comprising a sialic acid and/or sialc acid binding component even if Muster et al. is silent in sialic acid or sialic acid binding component. Therefore, the rejection is maintained.

Claims 21-26, 34-38 and 40 are still rejected under 35 U.S.C. 102(b) as being anticipated by Pales et al. (J. Inf. Dis. 1997, Vol. 176 (Suppl 1), pp. S45-S49).

Applicants argue that Pales et al. does not teach the claimed invention. Applicants' argument is fully considered; however, it is not found persuasive because the Pales et al do disclose the strategy for constructing an chimeric influenza virus vaccine (page S46 Fig. 1) and a serum immune response induced by using an immunogenic composition comprising chimeric influenza virus containing HIV-1 envelope protein gp41 epitope (page S48, Fig. 4). Therefore, the rejection is maintained.

Claims 21-26, 34-38 and 40 are still rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (J. Virol. 1993, Vol. 67, pp. 6659-6666).

Applicants argue the cited reference of Li et al. does not teach that the composition comprising sialic acid or sialic acid binding component. Applicants' argument is fully considered; however, it is not found persuasive because the fact is the composition disclosed in the specification is the same composition as taught by the prior art. Therefore, the rejection is maintained.

Claims 21-26, 34-38 and 40 are rejected still under 35 U.S.C. 102(a) as being anticipated by Chiba et al. (Arch Virol, August 1999, Vol. 144, pp. 1469-1485).

Applicants argue that the cited reference does not teach that the composition containing sialic acid and sialic acid nor an inactivated or attenuated target cell/virus. Applicants' argument is respectfully considered. However, it is not found persuasive because Chiba et al. disclose a

recombinant vaccinia virus expressing a chimeric influenza hemagglutinin (HA) protein, wherein the chimeric HA protein comprises 15 residues of the HIV envelope protein gp160. The said recombinant vaccinia virus (AVV) is an attenuated virus and the chimeric HA expression cassette inherently contains the sialic acid and sialic acid binding component as point out by Applicants in the response paper No. 14. Therefore, the rejection is maintained.

New Ground of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 **U.S.C. 112, first paragraph**, as **containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art** that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification was silent as to producing a protection in human and an animal deficient in CD^{4+} T cells.

Claim 21 is rejected under 35 U.S.C. § 112, first paragraph, as containing a new subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification was silent as to producing a protection in human deficient in CD^{4+} T cells. According to the specification, the injection of an immunogenic composition comprising a formalin inactivated influenza virus into a CD4+ T cell knockout mice (C57BL/6-$Cd4^{tm1Mak}$) and is able to induce an neutralizing antibody against the influenza virus and protect the immunized mice to survival after the lethal influenza challenge. However, there is no disclosure how human get protection from the immunization with the claimed composition.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
June 3, 2002

ALI R. SALIMI
PRIMARY EXAMINER